

REMARKS

Applicants acknowledge the current status of the claims, as reported in Office Action dated 07 October 2003. Claims 1-95 are pending; and claims 1-4, 9, 10, 12-31 and 89-95 are under consideration.

Applicants acknowledge Examiner's removal of objection to the specification, withdrawal of rejection of claims 1-4, 12-14 and 31 under 35 USC § 102(b), and withdrawal of rejection of claims 9 and 31 under 35 USC § 112, second paragraph.

Applicants thank the Examiner for the courtesy of an Examiner's interview, conducted on 16 December 2003, to discuss the bases of the outstanding objection and rejections to Applicants' application. This interview forms the bases for the present remarks.

Reconsideration and allowance of the pending claims in light of the following remarks are respectfully requested.

**Rejections under 35 USC §103(a)**

In the Office Action, at page 2, paragraph 5, claims 1-4, 12-14, 16-30, 31 and 89-95 are rejected under 35 USC § 103(a) as being unpatentable over Luger et al., in view of Green, Nguyen et al., Reisner et al., Barbas et al., WO 99/36569, WO 98/49286, WO98/31700, US 5580717, WO97/29131, Babcock et al., or Knappik et al.. The Examiner has continued to assert that it would be obvious to one skilled in the art to combine the teachings of Luger et al., with those of the references cited above to produce Applicants' claimed invention. Specifically, the Examiner asserts "motivation to combine the references is [...] provided by the teachings of Luger et al., that the antibody inhibits a molecule involved in inflammation, and the teachings of the other references as to how to make antibodies with improved characteristics". Applicants respectfully disagree.

**THE LEGAL STANDARD FOR *PRIMA FACIE* OBVIOUSNESS**

To establish a *prima facie* case of obviousness, three criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all claim limitations (MPEP §2143). Hindsight reconstruction of a claimed invention, absent a teaching or suggestion in the art is impermissible (MPEP §2142).

Specifically concerning impermissible hindsight reconstruction and the motivation to combine references, "case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." Regardless of the basis for motivation, "actual

evidence" is a requirement for a showing of motivation to combine references (*In Re Dembicza*k, 175 F.3d 994, Fed. Cir. 1999).

evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, although "the suggestion more often comes from the teachings of the pertinent references.". **The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence."**

(*Id.* at 1000; citations omitted; emphasis added)

Applicants' claimed invention is directed to a dual-specificity antibody, or antigen binding portion thereof, to IL-1 $\alpha$  and IL-1 $\beta$  wherein the antibody or antigen binding portion is not fully mouse.

**Luger et al.** teach a fully mouse monoclonal antibody which cross reacts with IL-1 $\alpha$  and IL-1 $\beta$ . Luger et al. do not teach, suggest, or motivate one of skill in the art with respect to:

- use of transgenic mice for the production of human or chimeric antibodies;
- use of SCID mice reconstituted with human peripheral blood lymphocytes for the production of human antibodies;
- use of a mouse treated with lethal total body irradiation, followed by radioprotection with bone marrow cells of a SCID mouse, followed by engraftment with functional human lymphocytes for the production of human antibodies;
- screening of recombinant antibody libraries for the production of antibodies;
- screening of recombinant antibody libraries displayed on the surface of yeast cells for the production of antibodies;
- screening of recombinant antibody libraries displayed on the surface of yeast cells or bacterial cells for the production of antibodies;
- screening of recombinant antibody libraries expressed as RNA-protein fusions for the production of antibodies;
- screening of recombinant antibody libraries for the production of antibodies;
- use of in vitro affinity maturation of a recombinant antibody library prepared from lymphoid cells of an animal previously immunized with the antigen to generate antibodies;
- selection of single cells secreting antibodies that bind antigen for the production of antibodies; method of generating chimeric or CDR-grafted antibodies;
- antibodies that are fully human, chimeric, CDR grafted or humanized.

In combination with the disclosure of **Luger et al.**, the Examiner cites the following:

**Green** discloses the use of transgenic mice that generate human antibodies.

**Nguyen et al.** disclose the use of SCID mice reconstituted with human peripheral blood lymphocytes for the production of human antibodies.

**Reisner et al.** disclose the use of a mouse treated with lethal total body irradiation, followed by radioprotection with bone marrow cells of a SCID mouse, followed by engraftment with functional human lymphocytes for the production of human antibodies.

**Barbas et al.** disclose the use of combinatorial (recombinant) antibody libraries on phage surfaces to generate antibodies in vitro.

**WO 99/36569** discloses the use of recombinant antibody libraries displayed on yeast cell surfaces to generate antibodies in vitro.

**WO 98/49286** discloses the use of recombinant antibody libraries displayed on yeast cell surfaces or bacterial cells to generate antibodies in vitro.

**WO 98/31700** discloses the use of recombinant antibody libraries expressed as RNA-protein fusions to generate antibodies in vitro.

**Dower et al.** disclose the use of recombinant antibody libraries to generate antibodies in vitro.

**Salfeld et al.** disclose the use of in vitro affinity maturation of a recombinant antibody library prepared from lymphoid cells of an animal previously immunized with the antigen to generate TNF $\alpha$  antibodies;

**Babcock et al.** disclose the method of isolating single cells secreting antibodies that bind antigen to generate monoclonal antibodies.

**Knappik et al.** disclose the method of generating chimeric or CDR-grafted antibodies.

**NONE OF THE ABOVE-CITED REFERENCES TEACH, SUGGEST, OR MOTIVATE ONE SKILLED IN THE ART APPLICANTS' METHOD OF MAKING A DUAL-SPECIFICITY ANTIBODY CAPABLE OF BINDING IL-1 $\alpha$  AND IL-1 $\beta$ .**

The Examiner asserts that Applicants cannot refute *prima facie* obviousness by attacking references individually where the rejections are based on combinations of references (citing, *inter alia*, *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375. (Fed. Cir. 1986)). In fact, Applicants assert that the Examiner has failed, initially, to satisfy the requirements of a *prima facie* case of obviousness.

In *Merck*, claims were directed to a method of treating depression with amitriptyline (or nontoxic salts thereof). The claims were rejected as *prima facie* obvious over prior art disclosures, which art explicitly stated; i) that amitriptyline is a compound known to possess psychotropic properties, ii) that imipramine is a structurally similar psychotropic compound known to possess antidepressive properties, iii) that amitriptyline and imipramine would be expected to have similar activity because the structural difference between the compounds involves a known bioisosteric replacement, AND iv) a **suggestion** for clinical testing of amitriptyline as an antidepressant. (see MPEP § 2143.02). In *Merck*, the court held that the claims were *prima facie* obvious over the prior art because there was a suggestion, and hence motivation, in the prior art to combine the references.

More recently, in *Dembiczak*, the invention at issue was a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern. Claim to the trash bag design was rejected as obvious in view of the cited art, which included:

- A holiday art handbook disclosing a "Crepe Paper Jack-O-Lantern" comprising orange crepe paper, construction paper cut-outs in the shape of facial features, and wadded newspaper as filling;
- A teacher's book disclosing a "paper bag pumpkin" made by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint;
- A US patent describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material; and
- Prior art "conventional" plastic lawn or trash bags.

The Board of Patent Appeals and Interferences (the Board) affirmed the obviousness rejection based on the combination of the references, stating that the references would have suggested the application of facial indicia to the prior art plastic trash bags.

On further review before the United States Court of Appeals For The Federal Circuit, the Court noted that the Board, rather than pointing to specific information in the references suggesting their combination, described, in detail, the similarities between the references and the claimed invention, noting that one reference or the other--in combination with each other and the conventional trash bags--described all of the limitations of the pending claims. The Court found that nowhere did the Board particularly identify any suggestion, teaching, or motivation to combine the references. The Court ultimately reversed the obviousness rejection "Because there is no evidence in the record of a suggestion, teaching, or motivation to combine the prior art references asserted against the pending claims. (*Id.* at 1003). A photocopy of the *Dembiczak* opinion, which is the current state of the law concerning

suggestion or motivation to combine references to establish obviousness, is provided herewith for the Examiner's review and consideration.

In the present rejection to Applicants' claimed invention, the Examiner maintains that one of ordinary skill is suggested or motivated to combine the cited references. The Examiner asserts that no knowledge other than that of the antibody of Luger et al. and the techniques taught by the other cited art references is required; that motivation to combine the references is "provided by the teachings of Luger et al., that the antibody inhibits a molecule involved in inflammation, and the teachings of the other references as to how to make antibodies with improved characteristics."

Applicants assert that the Examiner fails to provide the requisite "*clear and particular showing*" of any suggestion or motivation to combine the cited references; that, like the Board in Dembicza, the Examiner has combined the cited references one by one, and analyzed them limitation-by-limitation without demonstrating how and where the references teach, suggest, or motivate that they should be or could be combined to arrive at Applicants' invention. The assertion that the disclosure of IL-1 as "a molecule involved in inflammation", combined with a multitude of references disclosing "how to make antibodies with improved characteristics" is NOT a clear and particular teaching, suggestion, or motivation to one of skill in the art to make or to use the anti- IL-1 $\alpha$  /  $\beta$  dual-specificity antibody of the present invention.

Patchwork compilation of art is not sufficient (and is, in fact, improper) to establish a *prima facie* case of obviousness. Combination of this art using hindsight reconstruction is impermissible. Indeed, because of the Examiner's expertise and state-of-the-art knowledge in the biotechnology field of the present invention, actual evidentiary showing is "especially important" due to the fact that "the very ease with which the invention can be understood may prompt one '*to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher!*'" (*In Re Dembicza*, at 999).

Applicants maintain that in the absence of any clear and particular evidentiary showing of teaching, suggestion, or motivation to combine the cited establishment of a *prima facie* case of obviousness fails, and rejection of Applicants' invention as claimed is improper. In view of the foregoing remarks, Applicants respectfully request the withdrawal of the rejection to claims 1-4, 12-14, 16-30, 31 and 89-95 under 35 USC § 103(a) as being obvious.

#### Rejections under 35 USC §112, first paragraph

In the Office action at page 4, paragraph 6, claims 1-4, 9, 12-31 and 89-95 are rejected under 35 USC § 112, first paragraph as lacking enablement commensurate with the scope of the claims. The

Examiner 's basis for rejection resides in Applicants' working examples that one of four peptides generated antibodies capable of binding both IL-1 $\alpha$  and IL-1 $\beta$ , and that the specification as filed does not "provide guidance sufficient to allow an expectation of successful outcome on the part of the artisan." Applicants respectfully disagree.

#### **THE LEGAL STANDARD FOR ENABLEMENT**

Enablement under 35 USC § 112, first paragraph, requires that the Applicant teach the manner and process of making and using the claimed invention so as to enable any person skilled in the art to make and use the invention. It is well settled that enabling disclosure shall, *inter alia*, not require "undue experimentation" and shall provide for a "reasonable expectation of success". The test for undue experimentation "is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, OR if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.' " (*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, (CCPA 1976); See also MPEP §2164.06). The presence or number of inoperative embodiments within the scope of a claim does not render an invention nonenabled. An invention may be nonenabled if the number of inoperative combinations force a person skilled in the art to experiment unduly to practice the claimed invention. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. (*Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984); See also MPEP §2164.08(b)).

The criteria and test for enablement is particularly complex and important as applied to the field of biotechnology because it is both unpredictable and probabilistic. Most experimentation in biotechnology is a "numbers game", relying on a vast multitude of experimental events to achieve a few (or even one) successful outcomes. For example, the generation of a novel vector requires the successful incorporation of exogenous nucleic acid in to a vector construct. In reality, the vast majority of such genetic recombination attempts fail or are inoperative, with only a small number of operative constructs being generated and isolated. Similarly, vector transfection into a host cell succeeds only with immeasurable attempts to integrate a foreign nucleic acid into a host cell genome. The generation of hybridoma cell lines, capable of producing monoclonal antibodies, requires multiple individual experimental steps, each of which generates far more inoperative embodiments than operative embodiments. Despite this, the courts have recognized that such is the nature of biotechnology innovation, and that such experimentation is not undue to a person skilled in the art. Indeed this is holding in *In re Wands* (In Wands, the Applicant's specification provided sufficient enabling support as

to the Applicant's claim to immunoassay methods using a generic class of antibodies even though the specification disclosed only one deposited hybridoma cell line capable of producing a functional antibody). In fact, although a determination of enablement ultimately depends on the specific facts of each case, the USPTO, the Board of Patent Appeals & Interferences, and the courts have affirmed the general axiom that "once the antigen of interest is selected, the use of that antigen in the known method of Kohler and Milstein will result in the expected hybrid cell lines and the specific monoclonal antibodies, and thereby render antibodies to any known antigen easily enabled. (*Ex parte Erlich*, 3 USPQ2d 1011, (Bd. Pat. App. & Inter. 1986); see also *Johns Hopkins University v. CellPro*, 931 F.Supp. 303 (Dist. Del. 1996), and *Noelle v. Lederman*, Interference No. 104,415, Docket No. 02-1187 (Fed. Cir. decided 20 Jan 2004).

The present application is analogous to the above examples, wherein the specification as filed satisfies both of the alternative criterion sufficient for enablement. The specification as filed "provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed", AND the experimentation is in fact "merely routine".

Applicants teach how to make antigens. Applicants respectfully draw the Examiner's attention to pages 7-11 and pages 47-49 of the specification as filed. Applicants teach how to generate antibodies (see pages 11-31 of the specification as filed). Applicants teach how to screen and identify dual-specificity antibodies using binding assays (see pages 31-33 of the specification as filed). All of the techniques taught and described in the specification are disclosed in such clear and detailed manner as to enable one skilled in the art to generate, to screen, to isolate (operable from inoperable embodiments), and to use a dual specific antibody to any antigenic sequence selected by the practitioner.

The Examiner asserts that since three out of four examples of peptides disclosed by the Applicant did not yield antibodies capable of binding both IL-1 $\alpha$  and IL-1 $\beta$ , there is insufficient guidance to allow an expectation of success on the part of the artisan. Applicants respectfully submit that the Examiner's reasoning is flawed. Applicants "guidance to allow an expectation of success" is provided by the Applicants detailed disclosure, not by the number of operable or inoperable embodiments disclosed.

The Examiner would deny Applicants claim to their invention simply for disclosing inoperative embodiments as well as their operative claimed invention. Applicants purposefully disclose inoperative embodiments as a means of providing guidance to those skilled in the art how best to discern operative from inoperative embodiments. In return, the Examiner would penalize Applicants for disclosing too many inoperative embodiments (or any at all). Following such reasoning, any inventor of a novel recombinant cell line or monoclonal antibody would fail to enable the proper scope of their invention if they were to disclose a transfection efficiency or cell fusion success rate of less than 25%.

Applicants assert that satisfying the enablement requirement is not measured by disclosure of working examples, nor is the scope of their claimed invention limited by working examples. Not only does Applicants' teaching provide the practitioner sufficient guidance to comprehend the structural features necessary to generate dual-specificity antibodies to IL-1 $\alpha$  and IL-1 $\beta$ , but it also enables the practitioner to distinguish working from non-working embodiments. Contrary to the Examiner's assertion that a large number of peptides will have to be screened to generate dual-specificity antibodies, Applicants' disclosure gives proper and sufficient guidance such that only a reasonable number of peptides will have to be screened to obtain dual-specificity antibodies to IL-1 $\alpha$  and IL-1 $\beta$  with specificities described in the specification as filed. Indeed, a success rate of one in four (i.e., 25% success rate) is hardly burdensome experimentation in any field of endeavor. Notwithstanding this, the quantity of experiments is not determinative for 'undue experimentation'. One of ordinary skill in the art will recognize that the amount of experimentation needed is routine and by no means undue.

In view of the foregoing remarks, Applicants respectfully request the withdrawal of the rejection to claims 1-4, 9, 12-31 and 89-95 under 37 USC § 112 first paragraph.

In the Office action at page 5, paragraph 7, claims 4, 12-15 and 19-24 are rejected under 35 USC §112, first paragraph because the specification, while being enabling for methods of making antibodies that are not fully mouse *in vitro*, in transgenic or irradiated mice, and in animals other than mice, does not reasonably provide enablement for the methods as they broadly encompass mouse-generated antibodies. Applicants respectfully disagree.

Applicants previously amended the method of claim 4 such that the dual specificity antibody capable of binding IL-1 $\alpha$  and IL-1 $\beta$  obtained from the antibody repertoire exposed to an antigen comprising common structure features of IL-1 $\alpha$  and IL-1 $\beta$ , is not fully mouse. As discussed during the Examiner's interview of 16 December 2003, Applicants' previously presented claim amendment expressly limits the scope of the invention to antibodies that are not fully mouse. One of ordinary skill in the art will appreciate that Applicants' invention does not encompass a fully mouse dual specificity antibody capable of binding IL-1 $\alpha$  and IL-1 $\beta$ . Applicants believe that the Examiner and Applicants' representative reached an accord on this issue during their interview of 16 December 2003.

In view of the foregoing remarks, Applicants respectfully request the withdrawal of the rejection to claims 4, 12-15 and 19-24 under 37 USC § 112, first paragraph.

#### Allowable Subject Matter

Applicants acknowledge Examiner's indication that Claim 10 would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims. In view of the

remarks presented above, Applicants respectfully submit that all rejections to the claims set forth in the Office Action of 07 October 2003 have been avoided or overcome, and consequently the present objection to Claim 10 is subject for removal.

**Conclusion**

In view of the foregoing remarks, Applicants believe that all objections and rejections set forth in the Office Action of 07 October 2003 have been avoided or overcome, and consequently the application is in condition for allowance. Reconsideration and removal of the rejections, and allowance of the pending amended claims are, therefore, respectfully requested.

Respectfully submitted,



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LEXSEE 175 F.3D 994

IN RE ANITA DEMBICZAK and BENSON ZINBARG, Appellants.

98-1498

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

*175 F.3d 994; 1999 U.S. App. LEXIS 8109; 50 U.S.P.Q.2D (BNA) 1614*

April 28, 1999, Decided

**PRIOR HISTORY:** [\*\*1]Appealed from: Patent and Trademark Office Board of Patent Appeals and Interferences. (Serial No. 08/427,732).

**DISPOSITION:** REVERSED.

**CASE SUMMARY:**

**PROCEDURAL POSTURE:** Appellants, patent applicants, challenged a decision of the Patent and Trademark Office Board of Patent Appeals and Interferences that rejected all pending claims and double patenting in their application.

**OVERVIEW:** The patent appeals board (board) sustained and rejected all pending claims to appellants' claims in their patent application for a large trash bag made of orange plastic that when filled with trash or leaves would resemble a Halloween-style pumpkin, or jack-o'-lantern. Appellants challenged the board decision in the federal courts contending error in rejection of their pending claims and for obviousness-type double patenting. The court found no evidence in the record of a suggestion, teaching, or motivation to combine the prior art references asserted against the pending claims and reversed obviousness rejections. Concluding that there was no *prima facie* case against appellants, the court reversed the board's sustainment of their pending claims. The court further found, after *de novo* review, that the board had misapprehended the test for obviousness-type double patenting. Because the pending utility claims did not render obvious the design patents, the double patenting rejections were also improperly denied. The court reversed as to the double patenting rejections. The board decisions against appellant patent applicants were reversed.

**OUTCOME:** The court reversed the patent appeals board decision and double patenting rejections against the appellants, patent applicants, because the board erred in sustaining rejections of the pending claims as obvious and misapprehended the test for obviousness-type double patenting.

**LexisNexis (TM) HEADNOTES - Core Concepts:**

***Patent Law > Nonobviousness > Tests & Proof of Obviousness***

[HN1] A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *35 U.S.C.S. § 103(a)*.

***Patent Law > Nonobviousness > Tests & Proof of Obviousness***

[HN2] The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness.

***Patent Law > Jurisdiction & Review > Standards of Review***

[HN3] A reviewing court will review the ultimate determination of obviousness without deference to the patent appeals board, while examining any factual findings for clear error.

175 F.3d 994, \*; 1999 U.S. App. LEXIS 8109, \*\*;  
50 U.S.P.Q.2D (BNA) 1614

**Patent Law > Nonobviousness > Tests & Proof of Obviousness**

[HN4] Measuring a claimed invention against the standard established by 35 U.S.C.S. § 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in the case of less technologically complex inventions.

**Patent Law > Nonobviousness > Tests & Proof of Obviousness**

[HN5] The best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.

**Patent Law > Nonobviousness > Tests & Proof of Obviousness**

[HN6] Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability, the essence of hindsight.

**Patent Law > Nonobviousness > Tests & Proof of Obviousness**

[HN7] Evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, although the suggestion more often comes from the teachings of the pertinent references.

**Patent Law > Nonobviousness > Tests & Proof of Obviousness**  
**Patent Law > Jurisdiction & Review > Standards of Review**

[HN8] The range of sources available does not diminish the requirement for actual evidence. That is, the showing must be clear and particular.

**Patent Law > Nonobviousness > Tests & Proof of Obviousness**

[HN9] Broad conclusory statements regarding the teaching of multiple references, standing alone, are not evidence. In addition to demonstrating the propriety of an obviousness analysis, particular factual findings regarding the suggestion, teaching, or motivation to combine serve a number of important purposes, including: (1) clear explication of the position adopted by the Examiner and the Board; (2) identification of the

factual disputes, if any, between the applicant and the Board; and (3) facilitation of review on appeal.

**Patent Law > Nonobviousness > Tests & Proof of Obviousness**

[HN10] Where the patent appeals board does not establish a prima facie case of obviousness, a reviewing court can reverse the obviousness rejections, and has no need to address the parties' arguments with respect to secondary factors.

**Patent Law > Nonobviousness > Double Patenting & Terminal Disclaimers**

[HN11] Obviousness-type double patenting is a judicially-created doctrine that seeks to prevent the applicant from expanding the grant of the patent right beyond the limits prescribed in Title 35. The doctrine prohibits claims in a second patent which define "merely an obvious variation" of an invention claimed by the same inventor in an earlier patent. Thus, unless a claim sought in the later patent is patentably distinct from the claims in an earlier patent, the claim must be rejected.

**Patent Law > Nonobviousness > Double Patenting & Terminal Disclaimers**

[HN12] The question of double patenting is one of law, which is to be reviewed de novo.

**Patent Law > Nonobviousness > Double Patenting & Terminal Disclaimers**

[HN13] The law provides that, in some very rare cases, obvious-type double patenting may be found between design and utility patents. Under this two-way test, the obviousness-type double patenting rejection is appropriate only if the claims of the two patents cross-read, meaning that the test is whether the subject matter of the claims of the patent sought to be invalidated would have been obvious from the subject matter of the claims of the other patent, and vice versa.

**Patent Law > Nonobviousness > Tests & Proof of Obviousness**

[HN14] In order for a design to be unpatentable because of obviousness, there must first be a basic design reference in the prior art, the design characteristics of which are "basically the same as the claimed design."

**COUNSEL:** David P. Gordon, of Stamford, Connecticut, argued for appellant. Of counsel was Thomas A. Gallagher, of Stamford, Connecticut.

John M. Whealan, Associate Solicitor, Office of the Solicitor, of Arlington, Virginia, argued for appellee. With him on the brief were Albin F. Drost, Acting Solicitor, and David R. Nicholson, Associate Solicitor.

**JUDGES:** Before MAYER, Chief Judge, MICHEL and CLEVENGER, Circuit Judges.

**OPINIONBY: CLEVENGER**

**OPINION: [\*996] CLEVENGER, Circuit Judge.**

Anita Dembiczak and Benson Zinbarg appeal the rejection, upheld by the Board of Patent Appeals and Interferences, of all pending claims in their Application No. 08/427,732. See *Ex Parte Dembiczak*, No. 96-2648, slip op. at 43 (May 14, 1998). Because the Board erred in sustaining rejections of the pending claims as obvious under 35 U.S.C. § 103(a) (Supp. 1998), and for obviousness-type double patenting, we reverse.

I

The invention at issue in this case is, generally speaking, a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled [\*\*2] with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern. As the inventors, Anita Dembiczak and Benson Zinbarg (collectively, "Dembiczak") note, the invention solves the long-standing problem of unsightly trash bags placed on the curbs of America, and, by fortuitous happenstance, allows users to express their whimsical or festive nature while properly storing garbage, leaves, or other household debris awaiting collection. Embodiments of the invention--sold under a variety of names, including Giant Stuff-A-Pumpkin TM, Funkins, Jack Sak TM, and Bag-O-Fun TM--have undisputedly been well-received by consumers, who bought more than seven million units in 1990 alone. Indeed, in 1990, the popularity of the pumpkin bags engendered a rash of thefts around Houston, Texas, leading some owners to resort to preventative measures, such as greasing the bags with petroleum jelly and tying them to trees. See R. Piller, "Halloween Hopes Die on the Vine," *Hous. Chron.*, Oct. 19, 1990, at 13A.

The road to profits has proved much easier than the path to patentability, however. In July 1989, Dembiczak filed a utility patent application generally directed to the pumpkin bags. [\*\*3] In a February 1992 appeal, the Board of Patent Appeals and Interferences ("the Board") reversed the Examiner's rejection, but entered new grounds for rejection. Dembiczak elected to continue prosecution, filing a continuation application to address the new grounds for rejection. Thereafter, the invention made a second appearance before the Board, in April 1993, when the Board both sustained the Examiner's rejection and again entered new grounds for rejection. Again, a continuation application was filed (the instant application). And again the Examiner's rejection was

appealed to the Board, which sustained the rejection in a May 14, 1998, decision. See *Dembiczak*, slip op. at 43.

A

The patent application at issue includes claims directed to various embodiments of [\*997] the pumpkin bag. Claims 37, 49, 51, 52, 58 through 64, 66 through 69, and 72 through 81 are at issue in this appeal. Though the claims vary, independent claim 74 is perhaps most representative:

74. A decorative bag for use by a user with trash filling material, the bag simulating the general outer appearance of an outer surface of a pumpkin having facial indicia thereon, comprising:

a flexible waterproof plastic [\*\*4] trash or leaf bag having

an outer surface which is premanufactured orange in color for the user to simulate the general appearance of the outer skin of a pumpkin, and having

facial indicia including at least two of an eye, a nose and a mouth on the orange color outer surface for forming a face pattern on said orange color outer surface to simulate the general outer appearance of a decorative pumpkin with a face thereon,

said trash or leaf bag having first and second opposite ends, at least said second end having an opening extending substantially across the full width of said trash or leaf bag for receiving the trash filling material,

wherein when said trash or leaf bag is filled with trash filling material and closed, said trash or leaf bag takes the form and general appearance of a pumpkin with a face thereon.

All of the independent claims on appeal, namely 37, 52, 72, and 74, contain limitations that the bag must be "premanufactured orange in color," have "facial indicia," have openings suitable for filling with trash material, and that when filled, the bag must have a generally rounded appearance, like a pumpkin. Independent claims 37, 52, and 72 add the [\*\*5] limitation that the bag's height must at least 36 inches. Claim 72 requires that the bag be made of a "weatherproof material," and claim 74, as shown above, requires that the bag be "waterproof."

Claim 52 recites a "method of assembling" a bag with the general characteristics of apparatus claim 37.

## B

The prior art cited by the Board includes:

- (1) pages 24-25 of a book entitled "A Handbook for Teachers of Elementary Art," by Holiday Art Activities ("Holiday"), describing how to teach children to make a "Crepe Paper Jack-O-Lantern" out of a strip of orange crepe paper, construction paper cut-outs in the shape of facial features, and "wadded newspapers" as filling;
- (2) page 73 of a book entitled "The Everything Book for Teachers of Young Children," by Martha Shapiro and Valerie Indenbaum ("Shapiro"), describing a method of making a "paper bag pumpkin" by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint;
- (3) U.S. Patent No. 3,349,991 to Leonard Kessler, entitled "Flexible Container" ("Kessler"), describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material;
- (4) [\*\*6] U.S. Patent No. Des. 310,023, issued August 21, 1990 to Dembiczkak ("Dembiczkak '023"), a design patent depicting a bag with a jack-o'-lantern face;
- (5) U.S. Patent No. Des. 317,254, issued June 4, 1991 to Dembiczkak ("Dembiczkak '254"), a design patent depicting a bag with a jack-o'-lantern face; and,
- (6) Prior art "conventional" plastic lawn or trash bags ("the conventional trash bags").

Using this art, the Board affirmed the Examiner's final rejection of all the independent claims (37, 52, 72, 74) under 35 U.S.C. § 103, [\*\*998] holding that they would have been obvious in light of the conventional trash bags in view of the Holiday and Shapiro references. The Board determined that, in its view of the prior art, "the only difference between the invention presently defined in the independent claims on appeal and the orange

plastic trash bags of the prior art and the use of such bags resides in the application of the facial indicia to the outer surface of the bag." Dembiczkak, slip op. at 18. The Board further held that the missing facial indicia elements were provided by the Holiday and Shapiro references' description of painting jack-o'-lantern faces on paper bags. See [\*\*7] id. at 18-19. Dependent claims 49 and 79, which include a "gussets" limitation, were considered obvious under similar reasoning, except that the references cited against them included Kessler. See id. at 7.

The Board also affirmed the Examiner's obviousness-type double patenting rejection of all the independent claims in light of the two Dembiczkak design patents ('023 and '254) and Holiday. See id. at 12. The Board held that the design patents depict a generally rounded bag with jack-o'-lantern facial indicia, and that the Holiday reference supplies the missing limitations, such as the "thin, flexible material" of manufacture, the orange color, the initially-open upper end, and the trash filling material. The Board also stated that the various limitations of the dependent claims--e.g., color, the inclusion of leaves as stuffing, and the dimensions--would all be obvious variations of the depictions in the Dembiczkak design patents. See id. at 8-9. In addition, using a two-way test for obviousness-type double patenting, the Board held that the claims of the Dembiczkak design patents "do not exclude" the additional structural limitations of the pending utility claims, [\*\*8] and thus the design patents were merely obvious variations of the subject matter disclosed in the utility claims. See id. at 11. The Board further upheld, on similar grounds and with the inclusion of the Kessler reference, the obviousness-type double patenting rejection of dependent claim 49. See id. at 12.

This appeal followed, vesting this court with jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) (1994).

## II

[HN1] A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); see *Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 U.S.P.Q. (BNA) 459, 465, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966). [HN2] The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. See *Graham*, 383 U.S. at 17-18, 148

*U.S.P.Q. (BNA)* [\*\*9] at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 U.S.P.Q.2D (BNA) 1123, 1128 (Fed. Cir. 1993). [HN3] We therefore review the ultimate determination of obviousness without deference to the Board, while examining any factual findings for clear error. See, e.g., *In re Zurko*, 142 F.3d 1447, 1459, 46 U.S.P.Q.2D (BNA) 1691, 1700 (Fed. Cir.) (en banc), cert. granted, 119 S. Ct. 401 (1998).

#### A

Our analysis begins in the text of section 103 quoted above, with the phrase "at the time the invention was made." For it is this phrase that guards against entry into the "tempting but forbidden zone of hindsight," see *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 873, 228 U.S.P.Q. (BNA) 90, 98 (Fed. Cir. 1985), overruled on other grounds by *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 46 U.S.P.Q.2D (BNA) 1097 [\*999] (Fed. Cir. 1998), when analyzing the patentability of claims pursuant to that section. [HN4] Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted [\*\*10] wisdom in the field. See, e.g., *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. (BNA) 303, 313 (Fed. Cir. 1983). Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." Id.

Our case law makes clear that [HN5] the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2D (BNA) 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2D (BNA) 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select [\*\*11] the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q.2D (BNA) 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2D (BNA) 1596, 1600 (Fed. Cir. 1988)

(evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 U.S.P.Q. (BNA) 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also *Graham*, 383 U.S. at 18, 148 U.S.P.Q. (BNA) at 467 ("strict observance" of factual predicates to obviousness conclusion required). [HN6] Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 U.S.P.Q. (BNA) 543, 547 (Fed. Cir. 1985) ("The invention [\*\*12] must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, the Board fell into the hindsight trap.

We have noted that [HN7] evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, see *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 U.S.P.Q.2D (BNA) 1626, 1630 (Fed. Cir. 1996), *Para-Ordnance Mfg. v. SGS Imports Intern., Inc.*, 73 F.3d 1085, 1088, 37 U.S.P.Q.2D (BNA) 1237, 1240 (Fed. Cir. 1995), although "the suggestion more often comes from the teachings of the pertinent references," *Rouffet*, 149 F.3d at 1355, 47 U.S.P.Q.2D (BNA) at 1456. [HN8] The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. See, e.g., *C.R. Bard*, 157 F.3d 1340 at 1352, 48 U.S.P.Q.2D (BNA) at 1232. [HN9] Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence." E.g., *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1578, 27 U.S.P.Q.2D (BNA) [\*13] 1129, 1131 (Fed. Cir. 1993) ("Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of [\*1000] material fact."); *In re Sichert*, 566 F.2d 1154, 1164, 196 U.S.P.Q. (BNA) 209, 217 (CCPA 1977) ("The examiner's conclusory statement that the specification does not teach the best mode of using the invention is unaccompanied by evidence or reasoning and is entirely inadequate to support the rejection."). In addition to demonstrating the propriety of an obviousness analysis, particular factual findings regarding the suggestion, teaching, or motivation to combine serve a number of important purposes, including: (1) clear explication of the position adopted by the Examiner and the Board; (2) identification of the factual disputes, if any, between the

applicant and the Board; and (3) facilitation of review on appeal. Here, however, the Board did not make particular findings regarding the locus of the suggestion, teaching, or motivation to combine the prior art references.

All the obviousness rejections affirmed by the Board resulted from a combination of prior art references, e.g., the conventional trash or yard bags, and the Holiday and Shapiro publications teaching [\*\*14] the construction of decorated paper bags. See Dembicza, slip op. at 6-7. To justify this combination, the Board simply stated that "the Holiday and Shapiro references would have suggested the application of . . . facial indicia to the prior art plastic trash bags." Id. at 18-19. However, rather than pointing to specific information in Holiday or Shapiro that suggest the combination with the conventional bags, the Board instead described in detail the similarities between the Holiday and Shapiro references and the claimed invention, noting that one reference or the other--in combination with each other and the conventional trash bags--described all of the limitations of the pending claims. See id. at 18-28. Nowhere does the Board particularly identify any suggestion, teaching, or motivation to combine the children's art references (Holiday and Shapiro) with the conventional trash or lawn bag references, nor does the Board make specific--or even inferential--findings concerning the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any other factual findings that might serve to support a proper obviousness [\*\*15] analysis. See, e.g., *Pro-Mold & Tool*, 75 F.3d at 1573, 37 U.S.P.Q.2D (BNA) at 1630.

To the contrary, the obviousness analysis in the Board's decision is limited to a discussion of the ways that the multiple prior art references can be combined to read on the claimed invention. For example, the Board finds that the Holiday bag reference depicts a "premanufactured orange" bag material, see Dembicza, slip op. at 21, finds that Shapiro teaches the use of paper bags in various sizes, including "large", see id. at 22-23, and concludes that the substitution of orange plastic for the crepe paper of Holiday and the paper bags of Shapiro would be an obvious design choice, see id. at 24. Yet this reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the Holiday and Shapiro references teach or suggest their combination with the conventional trash or lawn bags to yield the claimed invention. See *Rouffet*, 149 F.3d at 1357, 47 U.S.P.Q.2D (BNA) at 1459 (noting Board's failure to explain, when analyzing the prior art, "what specific understanding or technical principle . . . would have suggested the combination"). Because we do not discern any finding by [\*\*16] the Board that there was a suggestion, teaching, or motivation to combine the prior art references cited against the pending claims, the Board's conclusion of

obviousness, as a matter of law, cannot stand. See *C.R. Bard*, 157 F.3d at 1352, 48 U.S.P.Q.2D (BNA) at 1232; *Rouffet*, 149 F.3d at 1359, 47 U.S.P.Q.2D (BNA) at 1459; *Fritch*, 972 F.2d at 1265, 23 U.S.P.Q.2D (BNA) at 1783; *Fine*, 837 F.2d at 1075, 5 U.S.P.Q.2D (BNA) at 1600; *Ashland Oil*, 776 F.2d at 297, 227 U.S.P.Q. (BNA) at 667.

## B

The Commissioner of Patents and Trademarks ("Commissioner") attempts to justify the Board's decision on grounds [\*\*1001] different from that relied upon by the Board, arguing that one of ordinary skill in the art would have been motivated to combine the references. Of course, in order to do so, the Commissioner must do what the Board did not do below: make specific findings of fact regarding the level of skill in the art ("a designer and manufacturer of trash and leaf bags, particularly one specializing in the ornamental and graphic design of such bags"), Resp't Br. at 14, the relationship between the fields of conventional trash bags and children's crafts, respectively ("the artisan would also have been well aware of the ancillary, [\*\*17] corollary, and atypical uses of 'trash' bags such as their application in hobby and art projects"), Resp't Br. at 15, and the particular features of the prior art references that would motivate one of ordinary skill in a particular art to select elements disclosed in references from a wholly different field ("a designer and manufacturer of trash and leaf bags would have recognized the paper bag in Shapiro to be a trash bag and therefore would have been motivated to combine it with the admitted prior art plastic trash and leaf bags to arrive at the claimed invention"), Resp't Br. at 15. The Commissioner also appears to cite additional references in support of his obviousness analysis, noting that at least two design patents (in the record but not cited against the presently pending claims) teach the placement of "graphical information, including text, designs, and even facial indicia, to colored bags." Resp't Br. at 16. This new analysis, apparently cut from whole cloth in view of appeal, does little more than highlight the shortcomings of the decision below, and we decline to consider it. See, e.g., *In re Robertson*, 1999 U.S. App. LEXIS 3224, 169 F.3d 743, 746, [\*\*18] 49 U.S.P.Q.2D (BNA) 1949, 1951 (Fed. Cir. 1999) ("We decline to consider [the Commissioner's] newly-minted theory as an alternative ground for upholding the agency's decision."); *In re Soni*, 54 F.3d 746, 751, 34 U.S.P.Q.2D (BNA) 1684, 1688 (Fed. Cir. 1995); *In re Hounsfeld*, 699 F.2d 1320, 1324, 216 U.S.P.Q. (BNA) 1045, 1049 (Fed. Cir. 1983) (rejecting an "attempt[ ] by the Commissioner 'to apply a new rationale to support the rejection.'"); see also 35 U.S.C. § 144 (1994) (an appeal to the Federal Circuit "is taken on the record before The Patent and Trademark

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Office"). [HN10] Because the Board has not established a *prima facie* case of obviousness, see *In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2D (BNA) 1529, 1531 (Fed. Cir. 1993) ("The PTO bears the burden of establishing a case of *prima facie* obviousness."), we therefore reverse the obviousness rejections, and have no need to address the parties' arguments with respect to secondary factors.

### III

Dembiczak also asks this court to reverse the Board's rejection of the pending claims for [HN11] obviousness-type double patenting, which is a judicially-created doctrine that seeks to prevent the applicant from expanding the grant of the patent right beyond the [\*\*19] limits prescribed in Title 35. See, e.g., *In re Braat*, 937 F.2d 589, 592, 19 U.S.P.Q.2D (BNA) 1289, 1291-92 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 892, 225 U.S.P.Q. (BNA) 645, 648 (Fed. Cir. 1985). See also 35 U.S.C. § 154(a)(2) (Supp. 1998) (discussing patent term). The doctrine prohibits claims in a second patent which define "merely an obvious variation" of an invention claimed by the same inventor in an earlier patent. *Braat*, 937 F.2d at 592, 19 U.S.P.Q.2D (BNA) at 1292 (quoting *In re Vogel*, 57 C.C.P.A. 920, 422 F.2d 438, 441, 164 U.S.P.Q. (BNA) 619, 622 (CCPA 1970)). Thus, unless a claim sought in the later patent is patentably distinct from the claims in an earlier patent, the claim must be rejected. See *In re Goodman*, 11 F.3d 1046, 1052, 29 U.S.P.Q.2D (BNA) 2010, 2015 (Fed. Cir. 1993); *Vogel*, 422 F.2d at 441, 164 U.S.P.Q. (BNA) at 622. [HN12] This question is one of law, which we review *de novo*. See *Goodman*, 11 F.3d at 1052, 29 U.S.P.Q.2D (BNA) at 2015; *Texas Instruments Inc. v. United States Int'l Trade Comm'n*, 988 F.2d 1165, 1179, 26 U.S.P.Q.2D (BNA) 1018, 1029 (Fed. Cir. 1993).

#### [\*1002] A

[HN13] The law provides that, in some very rare cases, obvious-type double patenting may be found between design and utility patents. [\*\*20] See *Carman Indus., Inc. v. Wahl*, 724 F.2d 932, 939-40, 220 U.S.P.Q. (BNA) 481, 487 (Fed. Cir. 1983) (noting that, while theoretically possible, "double patenting is rare in the context of utility versus design patents"); *In re Thorington*, 57 C.C.P.A. 759, 418 F.2d 528, 536-37, 163 U.S.P.Q. (BNA) 644, 650 (CCPA 1969) (Double patenting between a design and utility patent is possible "if the features producing the novel aesthetic effect of a design patent or application are the same as those recited in the claims of a utility patent or application as producing a novel structure."); *In re Phelan*, 40 C.C.P.A. 1023, 205 F.2d 183, 98 U.S.P.Q. (BNA) 156 (CCPA 1953); *In re Barber*, 23 C.C.P.A. 834, 81 F.2d 231, 28 U.S.P.Q. (BNA) 187 (CCPA 1936); *In re Hargraves*, 19 C.C.P.A. 784, 53 F.2d 900, 11 U.S.P.Q. (BNA) 240

(CCPA 1931). In these cases, a "two-way" test is applicable. See *Carman*, 724 F.2d at 940, 220 U.S.P.Q. (BNA) at 487. Under this test, the obviousness-type double patenting rejection is appropriate only if the claims of the two patents cross-read, meaning that "the test is whether the subject matter of the claims of the patent sought to be invalidated would have been obvious from the subject matter of the claims of the [\*\*21] other patent, and vice versa." *Id.*, 220 U.S.P.Q. (BNA) at 487. See also *Braat*, 937 F.2d at 593, 19 U.S.P.Q.2D (BNA) at 1292 (explaining two-way test).

### B

In making its double patenting rejection, the Board concluded that all but one of the pending claims of Dembiczk's utility application would have been merely an obvious variation of the claims of the earlier-issued design patents--the Dembiczk '023 and '254 references--in light of the Holiday reference. The remaining claim, dependent claim 49, was judged obvious in light of the combination of the Dembiczk design patents, Holiday, and the Kessler reference.

Acknowledging that the two-way test was required by *Carman*, 724 F.2d at 940, 220 U.S.P.Q. (BNA) at 487, the Board concluded that "the design claimed in each of appellants' design patents does not exclude the features pertaining to the construction and color of the bag, the use of a plastic material for making the bag, the size or thickness of the bag . . . or the use of various types of filling material . . . . The particular details of the facial indicia would have been a matter of design choice as evidenced by the Holiday handbook," and that therefore, in view of Holiday, the claims of the [\*\*22] design patents were obvious variants of the pending utility patent claims. See Dembiczk, slip op. at 11. We disagree. [HN14] In order for a design to be unpatentable because of obviousness, there must first be a basic design reference in the prior art, the design characteristics of which are "basically the same as the claimed design." *In re Borden*, 90 F.3d 1570, 1574, 39 U.S.P.Q.2D (BNA) 1524, 1526 (Fed. Cir. 1996); *In re Rosen*, 673 F.2d 388, 391, 213 U.S.P.Q. (BNA) 347, 350 (CCPA 1982). The phrase "having facial indicia thereon" found in the claims of the pending utility application is not a design reference that is "basically the same as the claimed design." *Borden*, 90 F.3d at 1574, 39 U.S.P.Q.2D (BNA) at 1526. In fact, it describes precious little with respect to design characteristics. The Board's suggestion that the design details were simply "a matter of design choice" evinces a misapprehension of the subject matter of design patents. E.g., *Carman*, 724 F.2d at 939 n.13, 220 U.S.P.Q. (BNA) at 486 n.13 ("Utility patents afford protection for the mechanical structure and function of an invention whereas design patent protection concerns the ornamental or aesthetic features of a

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design.") Indeed, we note [\*\*23] that the two design patents at issue here--the Dembiczkak '023 and '254 patents--were considered nonobvious over each other, and were even the subject of a restriction requirement. See 35 U.S.C. § 121 (1994) ("If two or more independent and distinct inventions are claimed in one [\*1003] application, the Commissioner may require the application to be restricted to one of the inventions."); 37 C.F.R. § 1.142. The position adopted by the Board--that a textual description of facial indicia found in the claims of the utility patent application makes obvious the specific designs claimed in the (patentably distinct) Dembiczkak design patents--would presumably render obvious, or even anticipate, all design patents where a face was depicted on a bag. But this, of course, is not the law; the textual description cannot be said to be a reference "basically the same as the claimed design," of the design patents at issue here. *Borden*, 90 F.3d at 1574, 39 U.S.P.Q.2D (BNA) at 1526 (internal quotation marks omitted). The Board's conclusion of obviousness is incorrect.

Because we find that the Board erred in concluding that the design patents were obvious variants of the pending utility claims, we need not address [\*\*24] the other prong of the two-way double patenting test--whether the pending utility claims are obvious variations of the subject matter claimed in the design patents. See *Carman*, 724 F.2d at 939, 220 U.S.P.Q. (BNA) at 487 (both prongs of the two-way test required for obviousness-type double patenting). The double patenting rejections are reversed.

#### IV

Because there is no evidence in the record of a suggestion, teaching, or motivation to combine the prior art references asserted against the pending claims, the obviousness rejections are reversed. In addition, because the Board misapprehended the test for obviousness-type double patenting, and because the pending utility claims do not render obvious the design patents, the double patenting rejections are also reversed.

REVERSED